

IBC Meeting
August 26, 2025 11AM, Zoom Virtual Meeting
Minutes

1. CALL TO ORDER:

1. The meeting was called to order at: 11:04am
2. In Attendance:
 - a. Ken Malcolm (Chair)
 - b. Cristina Penaranda (Co-Chair)
 - c. Doria Cladis (Non-Affiliated community member)
 - d. Tom Merry (Non-Affiliated community member)
 - e. Vanessa Rodriguez (Member/administrator)
 - f. Katie Kopf (Animal Expert/Veterinarian)
 - g. Matthew D. Rosenbaum (Animal Expert/Veterinarian)
 - h. Joanne E. Streib (Technical Member)
 - i. Peter Farina (Safety Officer)
3. Non Attendance:
4. Review and approval of the minutes: 7/22/25- The committee approved the minutes as submitted.

2. PROTOCOLS AND ADDENDA:

1. **BH-Bratcher-08-19. Preston Bratcher, PhD Triennial Review. Reviewer: Ken Malcolm**

Discussion: The reviewer presented the renewal submission to the committee noting, this study was reviewed at the pervious meeting and is now reviewing the revisions requested. The study will involve rDNA, infectious agents, human samples, live animals, and gene editing. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups (2) and biosafety levels (2). The study falls under sections III-D and III-D-2 of the NIH Guidelines A question was raised about manipulations in animals, it was noted that the study will be infecting and collecting cells, but cells or tissues will not be manipulated further.

Modifications and/or Clarification Requested:

1. In Section I.3 check the “recombinant DNA” box for work with CRISPR sgRNA; complete the Section II.7 and II.8 tables, as appropriate, specifying the CRISPR targets; and check the “A” boxes as appropriate for Section I.4. Please review Section V if using in animals and Appendix A, if using rDNA in unfixed flow analysis/sorting.
2. Section I.4, complete the Training plan.
3. In Section I.5 add category A, as appropriate
4. In the Section III.9 table for Mab and MAC, please specify the species. Also, in Section V.11.G, as appropriate.
5. In Section V.E, confirm if animals will be transferred to the lab. In V.G, list the specific species for use in animals. On the Handling Guide for MAC, check the precautions boxes as for Mab.
6. Provide individual lab signs and remove C120

Determination and vote: The committee voted to approve with modifications as indicated above.

Total: 9 **For: 9** Against: 0 Abstentions: 0

2. **BH-Chan.e-08-20. Edward Chan, MD- Addenda submission adding SARS-CoV-2. Reviewer: Cristina Penaranda**

Discussion: The reviewer presented the submission requesting the addition of SARS-CoV 2 into mice. New work being requested is in live animals. The additional work conducted will not change the section of the NIH guidelines the study falls under. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups (2) and biosafety levels (2).

The committee recommended enhanced BL 2 procedures after the mice have been harvested.

Modifications and/or Clarification Requested:

1. Revise addendum description to expand on the activities that will be conducted. Including but not limited to:
 - a. -where will mouse tissues be harvested?
 - b. -how will immune cell phenotyping be done? (if by flow cytometry, include that samples will be fixed).
 - c. -how will viral load be measured?
 - d. -whether virus will be propagated and if so, how
2. Section III.9.E: the committee recommends using Enhanced BL-2 practices for all work with SARS-CoV-2. This should be acknowledged in the PI comments section.
3. In mouse handling guide, BRC staff are able to change cages (standard husbandry). Clarification should be added to indicate whether lab personnel will be doing this and contact BRC to confirm.
4. Lab sign for D507 should be modified to add SARS-CoV-2 and recommended immunizations to original sign. Lab Sign for C120 is not needed.

A question was asked as to what a plaque assay is, which was described to the committee.

Determination and vote: The committee voted to approve with modifications as indicated above.

Total: 9 **For: 9** Against: 0 Abstentions: 0

3. **BH-Abbott-08-25. Derek Abbott, MD- New study. Reviewer: Ken Malcolm**

Discussion: The reviewer presented the new study submission to the committee noting the study will involve rDNA, infectious agents, human samples, lentiviral research, and gene editing. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups (2) and biosafety levels (2). The study falls under sections III-D, and III-D-2 of the NIH Guidelines.

It was noted that the vectors although second generation the vector has no rev gene which was noted to possibly be sufficient for designation as a lower risk group.

Modifications and/or Clarification Requested:

1. Main Registration Form
 - a. Add a training plan in question 4
 - b. Remove working with animals (D2) in section in question 5 and update the lab
 - c. Check box 3 in rDNA checklist and remove 5, 6, 7.
 - d. For question 7, lentiviral vectors for CRISPR targets should be listed separately from overexpression vectors, if appropriate. Change the Vector RG to RG2 for amphi/pantropic lentiviral vectors.\
 - e. Clarify if overexpression will be conducted (C.1)
 - f. Revise C.4, indicate the absent HIV genes, as described in Appendix C.
2. Appendix B
 - a. Indicate if both CRISPR and over expression are used.
3. Appendix C
 - a. C.A, remove the lentiviral overexpression system, as only gene editing procedures are described here.
4. Lab sign
 - a. Correct where human cell lines are listed.

Determination and vote: The committee voted to approve with modifications as indicated above.

Total: 9 **For: 9** Against: 0 Abstentions: 0

Cristina Penaranda left the call at 11:49 am

4. BH-Penaranda-08-22. Cristina Penaranda, PhD Triennial Review. Reviewer: Ken Malcolm

Discussion: The reviewer presented the renewal submission to the committee noting the study will involve rDNA, infectious agents, human samples, live animals, and flow cytometry. The study continues to fall under sections III-D, III-D-2, III-D-4 of the NIH Guidelines. The PI has submitted the appropriate appendices for this research and has appropriately identified the risk groups (2) and biosafety levels (2).

Modifications and/or Clarification Requested:

1. Main Registration Form
 - a. Section II.7, plasmid RG should be RG1
 - b. Section II.8, confirm that the E. Coli strains indicated in Section II are cloning strains and not clinical isolates. There is no requirement to include cloning strains of E. Coli.
2. Appendix A
 - a. Include samples with r/sNA (eg. Pa) separately
 - b. In B.ii, please clarify the use of gene edited cells; if CRISPR gene editing will be used
3. Appendix C

- a. Complete Appendix C and revise Section I; if Pa mutants are used please detail in this section if CRISPR gene editing will be used

Determination and vote: The committee voted to approve with modifications as indicated above.

Total: 8 **For: 8** Against: 0 Abstentions: 0

Cristina Penaranda was not present for the discussion or vote.

3. DMR APPROVALS:

1. BH-Manka-05-19. PI: Jennifer Taylor-Cousar, MD – Triennial review approved 08/08/2025.

4. APPROVALS:

1. BH-Dooms-05-22 Hans Dooms, PhD– Triennial review approved 8/04/2025.
2. BH-Gerber-03-19. PI: Anthony Gerber – Triennial review approved 5/15/2025.

5. SOPs and POLICIES:

None to Report

6. NEW BUSINESS

None to Report

7. OLD BUSINESS

None to Report

8. EDUCATION:

None to Report

9. MINOR ADMINISTRATIVE:

1. Note-to-Files (approved by Chairs):

None to Report

2. Personnel Updates:

- a) BH-Onofrei-02-25 PI: Claudia Onofrei, MD. Addition of Dusanka Mocevic approved 7/30/25.

3. Annual Reviews:

- a) BH-Day-07-21. PI: Brian Day, PhD. First Annual Review, approved 7/29/25
- b) BH-Rose-08-21. PI: Cecile Rose, MD. First Annual Review, removal of Kathy Pang addition of Elaine Epperson, approved 07/30/25.
- c) BH-Chan.e-08-20. PI: Edward Chan, MD. Second annual review 7/30/25.
- d) BH-Malcolm-08-20. PI: Ken Malcolm, PhD. Second annual review 8/04/25.
- e) BH-Taylor-Cousar-07-24. PI: Jennifer Taylor-Cousar, MD. First annual review 8/12/25.

4. Protocol Closures:

None to Report

5. Expiration:

None to Report

6. Memorandums of Understanding (MOUs)

None to Report

10. ADJOURNMENT:

Meeting Adjourned at: 11: 59 am

11. ATTACHMENTS

1. 8/26/2025 IBC Agenda
2. Minutes from the 7/22/25 IBC meeting
3. Submission Materials for section II
4. Approved materials for section III and IV

Respectfully submitted,

Signed by:

Ken Malcolm

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Ken Malcolm, PhD, IBC Chair

Signed by:

Vanessa Rodriguez

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Vanessa Rodriguez, IBC administrator